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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,472	01/03/2001	Guilherme Luiz Indig	09820.146	1825

25005 7590 05/24/2002

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EXAMINER

GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/753,472

Applicant(s)

INDIG, GUILHERME LUIZ

Examiner

Jerome D Goldberg

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Applicant's remarks are noted but the Group I invention is directed to removing the bone narrow from the body and <sup>then</sup> ~~taken~~ treating the <sup>bone</sup> ~~body~~ narrow to be employed as a bone narrow graft. The elected Group II invention is directed to treating cancer per se. Clearly these are two separate inventions and will support separate patents. According, the restriction requirement is deemed proper and made Final.

Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers disclosed the term "cancer cells", does not reasonably provide enablement for use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the term "cancer cells" in claims 6-10 lacks clear exemplary support in the specification as filed. The Dyer reference shows that crystal violet to be inactive against spontaneous mammary carcinoma in vivo (No. 3513, page 123) the invention commensurate in scope with these claims.

The cancer therapy art remains highly unpredictable, and no examples exist for efficacy of a triphenyl-methane dye with radiation against cancer cells generally. Therefore, based on the unpredictable nature of the invention and state of the prior art, lack of guidance and working examples, and extreme breadth of the claims, one skilled in this art could not use the entire scope of the claimed invention without undue

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experimentation. Changing the term "cancer cells" to the specific cancer cells disclosed would overcome this rejection.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-10 fail to recite the amount of the triphenyl-methane dye being employed. The Dyer reference teaches that crystal violet can be toxic at certain amounts (see Nos. 3514-3516, pages 123-124).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Dyer reference taken with the See-Lasley et al. reference.

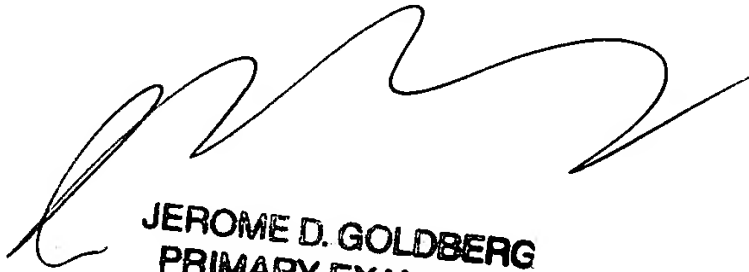
The Dyer reference teaches that applicant's claimed crystal violet is effective against carcinomas and sarcoma's in man by intratumoral administration. (See no. 3512, page 123). The See-Lasley et al. teaches the application radiation with chemotherapy. The references do not teach the combination together. Accordingly, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-cancer treatments together, where the results obtained thereby are no more the additive effects of the ingredients. In re Sussman, 1943 C.D. 518. Claims directed to a showing of greater than the additive effect would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermon Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday to Thursday 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/LR  
May 20, 2002



JEROME D. GOLDBERG  
PRIMARY EXAMINER